

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES,
AND PRODUCTS LIABILITY
LITIGATION**

MDL NO. 16-2738 (FLW) (LHG)

This document relates to:

Charles Fenstemaker Docket No. 3:16-cv-07418

STATUS REPORT

Pursuant to this Court's directive, Counsel submits the following report to inform the Court of the status of the above-referenced case(s).

I. Factual Background of the Cases

Johnson and Johnson's Baby Powder was introduced to the market in 1893. Since that time, Johnson & Johnson and its subsidiaries have marketed Baby Powder as a safe, mild product intended for use by both mothers and babies. Johnson's Baby Powder is composed, almost exclusively, of pure talc, a soft mineral comprised of magnesium, silicon, oxygen, and hydrogen. In 1966, Johnson & Johnson developed Shower to Shower, another talc-based body powder. Each of these products is marketed for feminine hygiene use, including perineal (genital) application, to limit perspiration, chafing, and other discomfort. Imerys Talc America, Inc. provides all of the talc used in Johnson & Johnson's talc-based body powders.

In 1971, the first study to indicate a possible association between the perineal application of talcum powder and ovarian cancer was conducted by W.J. Henderson in Cardiff, Wales.¹ In 1982, Dr. Daniel Cramer conducted the first case-control study of perineal talcum powder use

¹ W.J. Henderson, et al. *Talc and Carcinoma of the Ovary and Cervix*, 78 J. Obst. Gyn. Brit. Common. 266 (March 1971).

and ovarian cancer and found a significant increased risk of ovarian cancer among women who use talcum powders in the genital area.² Since 1982, numerous studies (27+ studies through October 2016)³, involving many of the most esteemed epidemiologists in the world, have consistently shown an increased risk of ovarian cancer associated with perineal talc use. Out of

² Cramer et al., *Ovarian Cancer and Talc: A Case-Control Study*, 50 *Cancer* 372 (1982).

³ Henderson, W.J., Joslin, C.A.F., Turnbull, A.C., and Griffiths, K. "Talc and Carcinoma of the Ovary and Cervix." *The Journal of Obstetrics and Gynaecology of the British Commonwealth*, March, 1971. Vol. 78. pp. 266-272; Cramer, D. W., W. R. Welch, R. E. Scully, and C. A. Wojciechowski. "Ovarian Cancer and Talc: A Case-Control Study." *Cancer* 50, no. 2 (July 15, 1982): 372-76.; Hartge, P., R. Hoover, L. P. Leshner, and L. McGowan. "Talc and Ovarian Cancer." *JAMA: The Journal of the American Medical Association* 250, no. 14 (October 14, 1983): 1844.; Whittemore, A. S., M. L. Wu, R. S. Paffenbarger, D. L. Sarles, J. B. Kampert, S. Grosser, D. L. Jung, S. Ballon, and M. Hendrickson. "Personal and Environmental Characteristics Related to Epithelial Ovarian Cancer. II. Exposures to Talcum Powder, Tobacco, Alcohol, and Coffee." *American Journal of Epidemiology* 128, no. 6 (December 1988): 1228-40.; Harlow, B. L., and N. S. Weiss. "A Case-Control Study of Borderline Ovarian Tumors: The Influence of Perineal Exposure to Talc." *American Journal of Epidemiology* 130, no. 2 (August 1989): 390-94.; Harlow, B. L., D. W. Cramer, D. A. Bell, and W. R. Welch. "Perineal Exposure to Talc and Ovarian Cancer Risk." *Obstetrics and Gynecology* 80, no. 1 (July 1992): 19-26.; Tzonou, A., A. Polychronopoulou, C. C. Hsieh, A. Rebelakos, A. Karakatsani, and D. Trichopoulos. "Hair Dyes, Analgesics, Tranquilizers and Perineal Talc Application as Risk Factors for Ovarian Cancer." *International Journal of Cancer. Journal International Du Cancer* 55, no. 3 (September 30, 1993): 408-10.; Chang, S., and H. A. Risch. "Perineal Talc Exposure and Risk of Ovarian Carcinoma." *Cancer* 79, no. 12 (June 15, 1997): 2396-2401.; Cook, Linda S., Mary L. Kamb, and Noel S. Weiss. "Perineal Powder Exposure and the Risk of Ovarian Cancer." *American Journal of Epidemiology* 145, no. 5 (March 1, 1997): 459-65.; Cramer, D. W., R. F. Liberman, L. Titus-Ernstoff, W. R. Welch, E. R. Greenberg, J. A. Baron, and B. L. Harlow. "Genital Talc Exposure and Risk of Ovarian Cancer." *International Journal of Cancer. Journal International Du Cancer* 81, no. 3 (May 5, 1999): 351-56.; Wong, C., R. E. Hempling, M. S. Piver, N. Natarajan, and C. J. Mettlin. "Perineal Talc Exposure and Subsequent Epithelial Ovarian Cancer: A Case-Control Study." *Obstetrics and Gynecology* 93, no. 3 (March 1999): 372-76.; Gertig, D. M., D. J. Hunter, D. W. Cramer, G. A. Colditz, F. E. Speizer, W. C. Willett, and S. E. Hankinson. "Prospective Study of Talc Use and Ovarian Cancer." *Journal of the National Cancer Institute* 92, no. 3 (February 2, 2000): 249-52.; Mills, Paul K., Deborah G. Riordan, Rosemary D. Cress, and Heather A. Young. "Perineal Talc Exposure and Epithelial Ovarian Cancer Risk in the Central Valley of California." *International Journal of Cancer. Journal International Du Cancer* 112, no. 3 (November 10, 2004): 458-64. doi:10.1002/ijc.20434.; Gates, Margaret A., Shelley S. Tworoger, Kathryn L. Terry, Linda Titus-Ernstoff, Bernard Rosner, Immaculata De Vivo, Daniel W. Cramer, and Susan E. Hankinson. "Talc Use, Variants of the GSTM1, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer." *Cancer Epidemiology, Biomarkers & Prevention: A Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology* 17, no. 9 (September 2008): 2436-44. doi:10.1158/1055-9965.EPI-08-0399.; Wu, Anna H., Pearce, Celeste L., Tseng, Chiu-Chen, Templeman, Claire, and Pike, Malcolm C. "Markers of inflammation and Risk of ovarian cancer in Los Angeles County."; Rosenblatt, Karin A., Noel S. Weiss, Kara L. Cushing-Haugen, Kristine G. Wicklund, and Mary Anne Rossing. "Genital Powder Exposure and the Risk of Epithelial Ovarian Cancer." *Cancer Causes & Control: CCC* 22, no. 5 (May 2011): 737-42. doi:10.1007/s10552-011-9746-3.; Houghton, Serena C., Katherine W. Reeves, Susan E. Hankinson, Lori Crawford, Dorothy Lane, Jean Wactawski-Wende, Cynthia A. Thomson, Judith K. Ockene, and Susan R. Sturgeon. "Perineal Powder Use and Risk of Ovarian Cancer." *Journal of the National Cancer Institute* 106, no. 9 (September 2014). doi:10.1093/jnci/dju208.; Cramer, Daniel W., Allison F. Vitonis, Kathryn L. Terry, William R. Welch, and Linda J. Titus. "The Association between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two US States." *Epidemiology (Cambridge, Mass.)*, December 17, 2015. doi:10.1097/EDE.0000000000000434.; Schildkraut, Joellen M., et al. "Association Between Body Powder Use and Ovarian Cancer: the African American Cancer Epidemiology Study (AACES). Published Online with the American Association for Cancer Research, May 12, 2016; Gonzalez, Nicole L., et al. "Douching, Talc Use, and Risk of Ovarian Cancer." *Epidemiology Publish Ahead of Print*, June 20, 2016.

these 27 studies, all but one of them found a statistically significant increased risk of ovarian cancer from talc use.

Beginning in September 1971, Johnson & Johnson developed a strategy to refute or discredit the Henderson findings. This included criticizing the Henderson study's techniques, validity, tissues, and references. Johnson & Johnson also focused on trying to prove the purity of the talc they used in their products, rather than performing research to determine if talc itself had any adverse effects when embedded in ovarian tissues. This effort continued for the next 10 years and only intensified after the 1982 study performed by Dr. Cramer. Numerous Johnson & Johnson and Imerys internal documents acknowledge the increasing health concerns involved with genital talc use and ovarian cancer.

In 2005, the International Agency for the Research on Cancer (IARC), an organization that is part of the World Health Organization, voted in favor of declaring perineal use of cosmetic grade talc a group 2B carcinogen, i.e., "possibly carcinogenic to human beings." IARC's rationale for this ruling was: "For perineal use of talc-based body powder, many case-control studies of ovarian cancer found a modest, but unusually consistent, excess in risk, although the impact of bias and potential confounding could not be ruled out." Since the IARC pronouncement, Imerys has placed a warning on the talc Material Safety Data Sheets (MSDS) that it sends to Johnson & Johnson, acknowledging that genital talc use may increase the risk of ovarian cancer.

Internal documents from Johnson & Johnson and Imerys Talc America demonstrate that, despite their knowledge of the risk of harm to women, these companies, along with their trade association, the Personal Care Products Council ("PCPC"), actively concealed information regarding the dangers of genital talcum powder use from consumers. Both companies have

actively attempted to influence regulatory agencies in an effort to prevent governmental regulation of talc use. This has included the formation of the Talc Interested Party Task Force, formed under the auspices of the Cosmetic Toiletry and Fragrance Association, for the purpose of defending talc-based products. Over the years this task force and other industry-sponsored groups have worked to influence the NTP, FDA, NIH, NIEHS, and other regulatory agencies.

Despite consistent evidence of a causal connection between perineal application of talcum powder and ovarian cancer, neither Johnson's Baby Powder nor Shower to Shower have been removed from the market or altered to remove talc as a main ingredient. Johnson & Johnson continues to sell these talc-based body powders without a consumer warning.

As a direct result of the Defendants' actions, untold numbers of women continue to use these products on a daily basis, and thousands of women have been diagnosed with cancer. Over the past few decades, this has led to countless avoidable deaths from ovarian cancer caused by the genital use of talcum powder.

II. Discovery in Federal Court

No discovery has taken place.

III. Settlement

The Parties have not entered into settlement discussions.

IV. Pending Motions

Defendants have filed motions to dismiss pursuant to Fed. R. Civ. P. R. 12(b)(2) or R. 12(b)(6). Plaintiff's oppositions have been filed. No decisions have been made.

V. Proposed Lead and Liaison Counsel

Counsel for all Plaintiffs with cases pending before this Court have met and conferred. There is unanimous agreement that Michelle A. Parfitt and P. Leigh O'Dell serve as Co-Lead

Counsel of the MDL. Counsel propose that Christopher M. Placitella be appointed as Liaison Counsel.

Ms. Parfitt and Ms. O'Dell will represent the interests of Plaintiffs who have alleged personal injury claims during the Organizational Conference.

VI. Proposed Agenda Items

Counsel for Plaintiffs propose the following agenda items that may be discussed during the Organizational Conference:

- A. Appointment of the Plaintiffs Steering Committee;
 - i. Appointment of Committee Chairs and Members;
 - ii. State/Federal Liaison
- B. Service of Papers.
 - i. Generate Corrected Service List;
 - ii. Potential for Use of a Counsel Contact Information Form;
 - iii. Potential for Stipulation Related to Waiver and Electronic Service Defendants
- C. Direct Filing Order
- D. Master Complaint/Short Form Complaints
- E. Master Answer/Short Form Answers
- F. Protective Order
- G. ESI Protocol
- H. Document Production Protocols
- I. Preservation/Extremis Depositions
- J. Tissue Preservation Protocol
- K. Plaintiff Fact Sheets/Defendant Fact Sheets

L. Role of Magistrate Judge

Dated: November 10, 2016

Respectfully submitted,

/s/

Hunter Shkolnik
Christopher LoPalo
Napoli Shkolnik PLLC
400 Broadhollow Road, Suite 305
Melville, NY 11747
(212) 397-1000

CERTIFICATE OF SERVICE

I hereby certify that on November 10, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

/s/
Christopher LoPalo
Napoli Shkolnik PLLC
400 Broadhollow Road, Suite 305
Melville, NY 11747
(212) 397-1000

ATTORNEY FOR PLAINTIFFS